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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,886	02/01/2006	David M. Neville	14028.0295U2	9182
36339 7590 06/16/2009 NATIONAL INSTITUTE OF HEALTH C/O Ballard Spahr Andrews & Ingersoll, LLP SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER MARVICH, MARIA	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 06/16/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/566,886	Applicant(s) NEVILLE ET AL.
Examiner MARIA B. MARVICH	Art Unit 1633

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 May 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-26.
Claim(s) withdrawn from consideration: 27-30.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s) _____.
13. ☒ Other: See Continuation Sheet

/Maria B Marvich/
Primary Examiner, Art Unit 1633

Continuation of 3. NOTE: Applicants have added claim 40 which recites that the mutation in the EF-2 protein is a substitution of Glycine to Arginine at position 701. The newly added claim requires new search and consideration such as 112 second considerations, for example, the claim does not indicate a sequence to which the amino acid 701 corresponds.

Continuation of 11. does NOT place the application in condition for allowance because: Consideration to applicants' arguments have been made regarding the rejection under 35 USC 112, first paragraph as well as the amendment to include the functional requirement of the mutation in EF-2. Such amendment provides the functional requirement of the mutation. However, given the rather large number of species of EF-2 and lack of structural requirements, the disclosure of the two species of mutants does not provide adequate description of the genus. However, limitation of the mutation to the catalytic region of the diphthamide domain of EF-2 should provide limiting structural requirement.

Applicants traverse the rejection under 35 USC 103 on pages 9-10 of the reply filed 5/12/09. Applicants argue that the steps referenced are related to harvesting conditions and not to methanol induction. However, the document teaches that methanol induction initiates at 26°C and harvesting at 10°C. Methanol induction is carried out during dropwise decrease of the temperature to 10°C wherein when the temperature reaches below 20°C, the methanol is cut off. This is evidenced by the teachings in column 7, "To minimize foaming, the methanol and pH loops are not shutoff until the temperature is below 20.degree. C." Hence, methanol administration, which is required for methanol induction continues until the temperature is below 20°C. While this step leads to the establishment of harvest conditions, they appear to be due to the inclusion of methanol part of the induction phase. Secondly, applicants' allegations of unexpected and surprising results are directed at claims that are not commensurate in scope with the claimed unexpected results. Specifically, applicants argue that the step of induction at 15°C lead to a synergistic increase in production yield. However, the claims are not limited to 15°C but rather recite quite broadly that the temperature must be below about 17°C. In fact, the yield at 17°C is not increased at all as demonstrated in figure 15B. Applicants use of the phrase about is not sufficient to distinguish the instant claims from the combination of Neville and Madsen et al.

Continuation of 13. Other: Had the amendment been entered the objection to claim 39 would have been overcome.

The specification uses the phrase figure 1a in the brief description of drawings and in the text. However, the figure is not labeled as a and b.